REMARKS

Applicants respectfully requests consideration of this application.

Claims 1 – 20, 22 – 28, and 31 – 35 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,906,579 of Vander Salm et al. (hereinafter "Vander Salm"). Claims 1, 2, 15, and 19 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,258,083 of Daniel et al. (hereinafter "Daniel"). Claims 21 and 29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Vander Salm and further in of view U.S. Patent 5,514,218 of Hillsman et al. (hereinafter "Hillsman"). Claim 30 has been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 36 – 39 have been allowed.

Claims 1 and 32 have been amended to define more properly pre-existing claim limitations. The amendments are supported by the specification and no new matter has been added. No claims have been canceled. No new claims have been added. As such, claims 1 – 39 remain pending in this application.

Amended independent claim 1 provides:

An apparatus comprising:

an intravascular device to perform a therapeutic treatment; and

at least one optical fiber disposed through the intravascular device, *the optical fiber configured to provide diagnostic information before and after the therapeutic treatment.* (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11 terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm, col. 6, lines 26 – 30, and FIG. 2). Connector 29 is operably connected through a standard fiber optic coupler 32 to a light source 40. The light provided to the balloon catheter is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip. For this reason, broadband white light is the preferred light for source 42. (Vander Salm, col. 6, lines 63 – 67). Vander Salm also discloses that by placing different colored filters at the light emitting regions 34a-34c, an emitted pattern of light of different colors can provide a visible indication of precisely which part of the balloon is being viewed through the blood vessel wall. (Vander Salm, col. 8, lines 7 – 11, and FIG. 4A). As such, the fiber optic light of Vander Salm is used as a visual aid during treatment. Nothing in Vander Salm discloses an optical fiber configured to provide diagnostic information before and after the therapeutic treatment.

Daniel discloses a viewing surgical scope with a distal end introducer assembly 102 and a main body assembly 104. A control handle 122 provides control of an optical fiber advancement member 442 of an optical fiber element 510 which transmits laser energy from a remote laser energy source. The bronchoscope's catheter 120 has multiple conduits which are accessed through the main body assembly 104 via multiple portal openings such as a fiber optic waveguide portal opening 124. These conduits accomplish functions such as illumination, aspiration or irrigation of target tissue at the scope's distal end at suction cup member 116. A hollow working channel is included

within the catheter 120 for introducing implements such as a laser energy delivery optical fiber. (Daniel, col. 7, lines 49 – 67, and FIG. 1A). As such, the optical fiber of Daniel is used during treatment only. Nothing in Daniel discloses an optical fiber configured to provide diagnostic information before and after the therapeutic treatment.

In contrast, amended independent claim 1 includes the limitation of "the optical fiber configured to provide diagnostic information before and after the therapeutic treatment." Therefore, Applicants respectfully submit that claim 1 is not anticipated by Vander Salm under 35 U.S.C. § 102(b) or Daniel under 35 U.S.C. § 102(e) and respectfully request the withdrawal of the rejection of the claim. Claims 2 – 14 depend either directly or indirectly from independent claim 1, and thus also include the limitation of "the optical fiber configured to provide diagnostic information before and after the therapeutic treatment." As such, Applicants respectfully submit that claims 2 – 14 are also not anticipated by Vander Salm under 35 U.S.C. § 102(b) or Daniel under 35 U.S.C. § 102(e) and respectfully request the withdrawal of the rejection of the claims.

Independent claim 15 provides:

> A catheter comprising:
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> a catheter shaft having an elongated outer member disposed about an tubular inner member and an intraluminal gap extending longitudinally between the outer member and the inner member; and
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> at least one optical fiber disposed within the intraluminal gap, *the catheter capable of both diagnostic and therapeutic purposes.*
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> (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11

terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm, col. 6, lines 26 – 30, and FIG. 2). Connector 29 is operably connected through a standard fiber optic coupler 32 to a light source 40. The light provided to the balloon catheter is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip. For this reason, broadband white light is the preferred light for source 42. (Vander Salm, col. 6, lines 63 – 67). Vander Salm also discloses that by placing different colored filters at the light emitting regions 34a-34c, an emitted pattern of light of different colors can provide a visible indication of precisely which part of the balloon is being viewed through the blood vessel wall. (Vander Salm, col. 8, lines 7 – 11, and FIG. 4A). As such, the catheter of Vander Salm is a treatment device. Nothing in Vander Salm discloses a catheter capable of both diagnostic and therapeutic purposes.

Daniel discloses a viewing surgical scope with a distal end introducer assembly 102 and a main body assembly 104. A control handle 122 provides control of an optical fiber advancement member 442 of an optical fiber element 510 which transmits laser energy from a remote laser energy source. The bronchoscope's catheter 120 has multiple conduits which are accessed through the main body assembly 104 via multiple portal openings such as a fiber optic waveguide portal opening 124. These conduits accomplish functions such as illumination, aspiration or irrigation of target tissue at the scope's distal end at suction cup member 116. A hollow working channel is included within the catheter 120 for introducing implements such as a laser energy delivery optical fiber. (Daniel, col. 7, lines 49 – 67, and FIG. 1A). As such, the optical fiber of

Daniel is used during treatment only. Nothing in Daniel discloses a catheter capable of both diagnostic and therapeutic purposes.

In contrast, independent claim 15 includes the limitation of "the catheter capable of both diagnostic and therapeutic purposes." Therefore, Applicants respectfully submit that claim 15 is not anticipated by Vander Salm under 35 U.S.C. § 102(b) or Daniel under 35 U.S.C. § 102(e) and respectfully request the withdrawal of the rejection of the claim. Claims 16 – 20 depend either directly or indirectly from independent claim 15, and thus also include the limitation of "the catheter capable of both diagnostic and therapeutic purposes." As such, Applicants respectfully submit that claims 16 – 20 are also not anticipated by Vander Salm under 35 U.S.C. § 102(b) or Daniel under 35 U.S.C. § 102(e) and respectfully request the withdrawal of the rejection of the claims.

Independent claim 22 provides:

A catheter comprising:

a catheter shaft having a tubular inner member coupled to an elongated outer member, *the catheter capable of both diagnostic and therapeutic purposes*;

an expandable member coupled to a distal portion of the catheter shaft; and

at least one optical fiber coupled to the expandable member. (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11 terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm,

col. 6, lines 26 – 30, and FIG. 2). Connector 29 is operably connected through a standard fiber optic coupler 32 to a light source 40. The light provided to the balloon catheter is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip. For this reason, broadband white light is the preferred light for source 42. (Vander Salm, col. 6, lines 63 – 67). Vander Salm also discloses that by placing different colored filters at the light emitting regions 34a-34c, an emitted pattern of light of different colors can provide a visible indication of precisely which part of the balloon is being viewed through the blood vessel wall. (Vander Salm, col. 8, lines 7 – 11, and FIG. 4A). As such, the catheter of Vander Salm is a treatment device. Nothing in Vander Salm discloses a catheter capable of both diagnostic and therapeutic purposes.

In contrast, independent claim 22 includes the limitation of "the catheter capable of both diagnostic and therapeutic purposes." Therefore, Applicants respectfully submit that claim 22 is not anticipated by Vander under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claims 23 – 25 depend either directly or indirectly from independent claim 22, and thus also include the limitation of "the catheter capable of both diagnostic and therapeutic purposes." As such, Applicants respectfully submit that claims 23 – 25 are also not anticipated Vander Salm under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claims.

Independent claim 26 provides:

An apparatus comprising:

a catheter comprising a catheter shaft having a lumen therein;

a sheath slidably disposed over the catheter shaft; the catheter shaft and the sheath defining an intraluminal gap extending longitudinally therebetween; and

at least one optical fiber disposed within the intraluminal gap, *the apparatus capable of both diagnostic and therapeutic purposes.* (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11 terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm, col. 6, lines 26 – 30, and FIG. 2). Connector 29 is operably connected through a standard fiber optic coupler 32 to a light source 40. The light provided to the balloon catheter is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip. For this reason, broadband white light is the preferred light for source 42. (Vander Salm, col. 6, lines 63 – 67). Vander Salm also discloses that by placing different colored filters at the light emitting regions 34a-34c, an emitted pattern of light of different colors can provide a visible indication of precisely which part of the balloon is being viewed through the blood vessel wall. (Vander Salm, col. 8, lines 7 – 11, and FIG. 4A). As such, the catheter of Vander Salm is a treatment device. Nothing in Vander Salm discloses an apparatus capable of both diagnostic and therapeutic purposes.

In contrast, independent claim 26 includes the limitation of "the apparatus capable of both diagnostic and therapeutic purposes." Therefore, Applicants

respectfully submit that claim 26 is not anticipated by Vander under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claim 27 depends from independent claim 26, and thus also includes the limitation of "the apparatus capable of both diagnostic and therapeutic purposes." As such, Applicants respectfully submit that claim 27 is also not anticipated Vander Salm under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim.

Independent claim 28 provides:

A catheter comprising:

a catheter shaft having an inner member coupled to an outer member, the catheter shaft having a lumen longitudinally therethrough;

an elongated member disposed within the lumen; and

at least one optical fiber disposed within the elongated member. (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11 terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm, col. 6, lines 26 – 30, and FIG. 2). Light fiber 42 is mounted in the inflation lumen or an adjacent lumen and extends longitudinally through said lumen (dashed lines). Fiber 42 carries light from light source 40 distally through the lumen to one or more emission regions such as the end face 42a, or regions 36, of which examples are shown in FIGS. 2A-B and 4B-C. In one embodiment, monitor lumen 44 operably connects to monitor system 46 via port 38 and connector tube 30. (Vander Salm, col. 7, lines 31 – 39, and FIG. 3). Nothing in Vander Salm teaches a catheter shaft having an inner member

coupled to an outer member.

In contrast, independent claim 28 includes the limitation of "a catheter shaft having an inner member coupled to an outer member." Therefore, Applicants respectfully submit that claim 28 is not anticipated by Vander under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claim 31 depends from independent claim 28, and thus also includes the limitation of "a catheter shaft having an inner member coupled to an outer member." As such, Applicants respectfully submit that claim 31 is also not anticipated Vander Salm under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim.

Independent claim 32 provides:

> A system for sensing vessel and blood characteristics, the system comprising:
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> a data processing system; and
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> an apparatus coupled to the data processing system, the apparatus comprising an intravascular device to perform a therapeutic treatment and at least one optical fiber disposed therethrough, *the optical fiber configured to provide diagnostic information before and after the therapeutic treatment.*
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> (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11 terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm, col. 6, lines 26 – 30, and FIG. 2). Connector 29 is operably connected through a standard fiber optic coupler 32 to a light source 40. The light provided to the balloon

catheter is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip. For this reason, broadband white light is the preferred light for source 42. (Vander Salm, col. 6, lines 63 – 67). Vander Salm also discloses that by placing different colored filters at the light emitting regions 34a-34c, an emitted pattern of light of different colors can provide a visible indication of precisely which part of the balloon is being viewed through the blood vessel wall. (Vander Salm, col. 8, lines 7 – 11, and FIG. 4A). As such, the catheter of Vander Salm is a treatment device. Nothing in Vander Salm discloses an optical fiber configured to provide diagnostic information before and after the therapeutic treatment.

In contrast, amended independent claim 32 includes the limitation of "the optical fiber configured to provide diagnostic information before and after the therapeutic treatment." Therefore, Applicants respectfully submit that claim 32 is not anticipated by Vander under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claim 33 depends from independent claim 32, and thus also includes the limitation of "the apparatus capable of both diagnostic and therapeutic purposes." As such, Applicants respectfully submit that claim 33 is also not anticipated Vander Salm under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim.

Independent claim 34 provides:

A method of sensing vessel and blood characteristics, the method comprising:

inserting an apparatus into a vasculature of a patient, the apparatus comprising a intravascular device to perform a therapeutic treatment and at

least one optical fiber disposed within the intravascular device, the optical fiber to transmit a light radiation signal therethrough;

advancing the apparatus to a location in the vasculature;

operating a data processing system coupled to the apparatus to transmit a plurality of light radiation signals to the location in the vasculature and a plurality of reflected light radiation signals to a detector in the data processing system; and

processing the plurality of reflected light radiation signals to determine vessel and blood characteristics. (emphasis added)

Vander Salm discloses a balloon catheter for controlling hemorrhaging during surgery by positioning a balloon at a point in a blood vessel. The catheter body 11 terminates in a coupling 27, typically a short handle assembly, which operably connects the lumens of the catheter to connector tubes or lines 28, 29 and 30. (Vander Salm, col. 6, lines 26 – 30, and FIG. 2). Connector 29 is operably connected through a standard fiber optic coupler 32 to a light source 40. The light provided to the balloon catheter is emitted at or near the balloon and serves as a visual aid to mark the location of the balloon at the catheter tip. For this reason, broadband white light is the preferred light for source 42. (Vander Salm, col. 6, lines 63 – 67). Vander Salm also discloses that by placing different colored filters at the light emitting regions 34a-34c, an emitted pattern of light of different colors can provide a visible indication of precisely which part of the balloon is being viewed through the blood vessel wall. (Vander Salm, col. 8, lines 7 – 11, and FIG. 4A). As such, the catheter of Vander Salm is a treatment device. Nothing in Vander Salm discloses processing the plurality of reflected light radiation signals to determine vessel and blood characteristics.

In contrast, amended independent claim 34 includes the limitation of "processing

the plurality of reflected light radiation signals to determine vessel and blood characteristics." Therefore, Applicants respectfully submit that claim 34 is not anticipated by Vander under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim. Claim 35 depends from independent claim 34, and thus also includes the limitation of "processing the plurality of reflected light radiation signals to determine vessel and blood characteristics." As such, Applicant respectfully submits that claim 35 are also not anticipated Vander Salm under 35 U.S.C. § 102(b) and respectfully request the withdrawal of the rejection of the claim.

Claims 21 and 29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Vander Salm and further in of Hillsman. Claim 21 depends from independent claim 15 and thus includes the limitation of "the catheter capable of both diagnostic and therapeutic purposes." Claim 29 depends from independent claim 28 and thus includes the limitation of "a catheter shaft having an inner member coupled to an outer member." As discussed above, Vander Salm does not teach or suggest these limitations.

Hillsman teaches a fiber optic guidewire in which laser energy is conveyed by the optical fibers to ablate an obstruction. Guide wire assembly 22 comprises optical fiber bundle 24 disposed within jacket 26. Guide wire 10 may be advantageously used to ablate an intravascular occlusion and then to position a catheter for subsequent occlusion. In this technique, guide wire 10 is connected to a source of light energy such as a laser by way of proximal mount 16. (Hillsman, col. 8, lines 22 – 26). Nothing in Hillsman discloses or suggests a catheter capable of both diagnostic and therapeutic

purposes, or a catheter shaft having an inner member coupled to an outer member. As such, Hillsman fails to cure the deficiencies of Vander Salm. Therefore, Applicants respectfully submit that claims 21 and 29 are not unpatentable over Vander Salm in of Hillsman under 35 U.S.C. § 103(a), request removal of the rejection of the claims.

In conclusion, Applicants respectfully submit that in view of the amendments and arguments set forth herein, the applicable rejections have been overcome. If the allowance of these claims could be facilitated by a telephone conference, the Examiner is invited to contact Suk Lee at (408) 720-8300. If there are any additional charges, please charge our Deposit Account No. 02–2666.

Respectfully submitted,

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